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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,009	09/26/2003	Laurent Schaller	CSI-2027	7654

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JEFFREY J. HOHENSHELL  
710 MEDTRONIC PARKWAY  
MINNEAPOLIS, MN 55432

EXAMINER
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NGUYEN, TUAN VAN

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
09/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/672,009	Applicant(s) SCHALLER ET AL.	
	Examiner Tuan V. Nguyen	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 34-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on September 26, 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Amendment After Non-Final Rejection***

1. According to the Amendment After Non-Final Rejection applicants filed on July 31, 2007, applicant amended claims 4-5, 12-16, 18 and 33 to correct typographical errors. Examiner acknowledges the correction, no new matter is added.

### ***Response to Amendment***

2. Applicant's arguments with respect to claims 1, 17, 22, and 28 have been fully considered but they are not persuasive. With respect to arguments regarding claims 1, 17, 22, and 28 that Arcia and Miller references fail to disclose both clips and barbs, therefore, the combination of Arcia and Miller is improper. Examiner respectfully traverses the applicant's remarks: Arcia clearly discloses needles 270, wherein the needles piercing through the graft, therefore, the needles is equivalent to the barbs structure as claimed by the applicant (see Office Action mailed on January 22, 2007, paragraph 6). Miller discloses (see Figs. 5A-5F and 13-34; see col. 7, line 46 to col. 8, line 40 and col. 12, line 50 to col. 13, line 25) anastomosis device 50, 170 comprising: one or plurality of clip 10, 236 slidably and disposed in tube 51, wherein the clips is made from Nitinol, which referred to as shape memory (see col. 5, lines 55-60), wherein the clip assume a shape that automatically applies to the layers of tissue an appropriate hemostatic compression which is relatively independent of tissue thickness and the fastener

or clip is a suitable replacement for conventional non bio-absorbable sutures and staples in certain clinical application (see col. 3, lines 54-60), thus Miller clearly discloses the clip 10 is equivalent to the self-closing clip as claimed by the applicant. Miller also discloses each clip being releasably coupled to said support structure by plunger 52; and hollow needle 54 or barb, wherein the clip 10 unattached to the needle and moved independently with hollow needle 54 or barb.

Therefore it would have been obvious to one of ordinary skill in the art to replace needle 270 and suture 272 of Arcia with hollow needle 54 and clip 10 as disclosed by Miller for two purpose: to eliminate the tying knot because tying knot is time consuming and to gain the advantage of the clip assume a shape that automatically applies to the layers of tissue an appropriate hemostatic compression which is relatively independent of tissue thickness as suggested by Miller (see col. 3, lines 54-60).

3. With respect to the limitation "a first plurality of paths and a second plurality of parth" as recited in claim 17, Arcia clearly discloses the (see Figs. 10, 11 and 13) the drive tubes 260, each includes first portion 240 of guide channel or first path and second portion 250 or second path. Examiner suggests applicant further define the structure of the first path and second path as shown in Figs. 6A-6D of the instant application to overcome the rejection based on the combination of Arcia and Miller references.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arcia et al. (U.S. 6,358,258) in view of Miller et al. (U.S. 6,709,442).**
7. Referring to claims **1-16, 17-21, 22-30 and 31-33**, Arcia discloses (see Figs. 8-12) an anastomosis device 200 comprising: a shaft or support structure 210; one or plurality of Nitinol needles 270 or barb, wherein the needles or barbs slidably coupled to the channels or tubular members 240, 250, the needles 270 or barbs are for supporting graft G to the device (see Fig. 11) and for deploying of suture 272 to secure the graft to other vessel; drive tubes 260 coupled to a thumb cap 232, wherein the thumb cap and drive tubes are for simultaneously deploying of

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flexible needles out of channel 240, 250 or tubular members (see col. 9, line 16 to col. 10, line 48). With respect to **claims 26 and 30**, Arcia discloses the suture 272 is connected to the proximal end of needle 270 and the other end of suture is connected and stored in cap 232, thus, the needle 272 can be retracted into the tubular member 240, 250 if the surgeons desired to do so or if he/she feels that the needle 272 is not deployed to proper location (see col. 9, lines 54-62). Arcia discloses the invention substantially as claimed except for the clips being separate from the barbs and movable independently of the barbs.

8. Still referring to claims **1-16, 17-21, 22-30 and 31-33**, However, Miller discloses (see Figs. 5A-5F and 13-34) anastomosis device 50, 170 comprising: a support structure 51, 57 or 226, 218, 220; one or plurality of self-closing clip 10, 236 slidably and disposed in tube 51 or plurality of tube 230 (or first plurality of member), wherein the clips is shape memory clip and the clips assume a shape that automatically applies to the layers of tissue an appropriate hemostatic compression which is relatively independent of tissue thickness and the fastener or clip is a suitable replacement for conventional non bio-absorbable sutures and staples in certain clinical application (see col. 3, lines 54-60), each clip being releasably coupled to said support structure by plunger 52, 238; a pusher, 60, 210 is connected to plunger 52, 238; and the clips can be deployed simultaneously; and hollow needle 54 or barb, wherein the clip 10 unattached to the needle and moved independently with hollow needle 54 or barb (see col. 7, line 46 to col. 8, line 40 and col. 12, line 50 to col. 13, line 25).

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9. Still referring to claims **1-16, 17-21, 22-30 and 31-33**, therefore, it would have been obvious to one of ordinary skill in the art to replace needle 270 and suture 272 of Arcia with hollow needle 54, clip 10, and pusher 52 as disclosed by Miller for two purposes: eliminating the tying knot because tying knot is time consuming and providing the advantage of the clip assume a shape that automatically applies to the layers of tissue an appropriate hemostatic compression which is relatively independent of tissue thickness as suggested by Miller (see col. 3, lines 54-60).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen  
September 21, 2007

  
ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER

1/22/07